K102426 P1/2

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

OCT 20 2010

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	August 12, 2010
Submitter:	GE Medical Systems *Information Technologies*, Inc. 8200 Tower Avenue Milwaukee, WI 53223
Primary Contact Person:	Mary Carter Regulatory Affairs Leader GE Healthcare 414-362-2626 414-362 2585
Secondary Contact Person:	David Wahlig Director, Regulatory Affairs GE Healthcare 414-362-3242 414-362 2585
Device: Trade Name:	CARESCAPE V100 Vital Signs Monitor
Common/Usual Name:	Physiological or Vital Signs Monitor, Patient Monitor
Classification Names:	21 CFR 870.2300
Product Code:	MWI
Predicate Device(s):	K073203 CARESCAPE V100 K011291 Exergen TemporalScanner Thermometer, SensorTouch K050230 TurboTemp Trio
Device Description:	The CARESCAPE V100 vital signs monitor provides a small, portable, easy-to-use monitoring alternative for sub-acute hospital and non-hospital settings. The monitor is for use on adult, pediatric, or neonatal patients—one at a time. The battery-operated monitor offers noninvasive determination of systolic blood pressure, diastolic blood pressure, mean arterial pressure, pulse rate, oxygen saturation, and temperature. Monitors are available with or without integrated printers as well as the following parameters and technologies. • NIBP, Pulse: SuperSTAT, Auscultatory, or Classic • SpO2: Ohmeda TruSignal, Nellcor OxiMax, or Masimo SET • Temperature: Alaris Turbo Temp, Alaris Tri-Site, or Exergen TemporalScanner Thermometer
Intended Use:	The CARESCAPE V100 Vital Signs Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature. The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. The CARESCAPE V100 Vital Signs Monitor can also be used in satellite areas, physicians' office, or alternate care settings.

Technology: The CARESCAPE V100 Vital Signs Monitor employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The CARESCAPE V100 Vital Signs Monitor and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, CARESCAPE V100 Vital Signs Monitor, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the CARESCAPE V100 Vital Signs Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Mary Carter
Regulatory Affairs Leader
GE Healthcare
GE Medical Systems Information Technologies, Inc.
8200 Tower Avenue
Milwaukee, WI 53223

OCT 2 0 2010

Re: K102426
Device Name: CARESCAPE V100 Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient physiological monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II (Two)
Product Codes: MWI, DQA, DXN, FLL
Dated: September 20, 2010
Received: October 8, 2010

Dear Ms. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K102426

OCT 2 0 2010

Device Name: CARESCAPE V100 Vital Signs Monitor

Indications for Use:

The CARESCAPE V100 Vital Signs Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature.

The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. The CARESCAPE V100 Vital Signs Monitor can also be used in satellite areas, physicians' office, or alternate care settings.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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